

INTERNATIONAL SEARCH REPORT

In **onal Application No**
PCT/IB2004/003077**A. CLASSIFICATION OF SUBJECT MATTER**
IPC 7 A61K9/107 A61K31/337 A61K38/13

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data, BIOSIS, MEDLINE**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------|--|-----------------------|
| P, X | EP 1 340 497 A (NOVAGALI SAS ;YISSUM RES DEV CO (IL)) 3 September 2003 (2003-09-03) paragraph '0025! paragraph '0048! claims examples ----- A | 1-21 |
| A | WO 02/43765 A (TRANSFORM PHARMACEUTICALS INC ;CHEN HONGMING (US)) 6 June 2002 (2002-06-06) page 4, line 31 – page 5, line 1 page 14, line 4 – line 21 See Formulations G,H,I,J,K ----- -/- | 1-21 |



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

26 October 2004

Date of mailing of the international search report

04/11/2004

Name and mailing address of the ISA

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------|--|-----------------------|
| A | US 6 509 370 B1 (GORE ASHOK Y ET AL) 21 January 2003 (2003-01-21) column 3, line 8 - column 4, line 8 column 6, line 42 - line 48 examples ----- | 1-21 |
| A | US 6 458 373 B1 (CONSTANTINIDES PANAYIOTIS P ET AL) 1 October 2002 (2002-10-01) column 3, line 45 - column 4, line 18 examples ----- | 1-21 |
| A | WO 99/45918 A (NAPRO BIOTHERAPEUTICS INC) 16 September 1999 (1999-09-16) page 3, line 3 - line 32 examples 8,10,11 ----- | 1-21 |
| A | US 2002/156124 A1 (MOROZOWICH WALTER ET AL) 24 October 2002 (2002-10-24) paragraph '0025! - paragraph '0030! paragraph '0033! - paragraph '0041! paragraph '0072! - paragraph '0079! ----- | 1-21 |
| A | WO 95/11039 A (HEXAL PHARMA GMBH ;KLOKKERS KARIN (DE); FISCHER WILFRIED (DE)) 27 April 1995 (1995-04-27) example 3 ----- | 1-21 |
| A | WO 00/78247 A (BAKER NORTON PHARMA) 28 December 2000 (2000-12-28) page 8, line 12 - page 9, line 6 page 10, line 18 - page 11, line 21 example 8 ----- | 1-21 |

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Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 21 because they relate to subject matter not required to be searched by this Authority, namely:
Although claim 21 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. Claims Nos.: 1-21 in part because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Although claim 21 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box II.1

Claims Nos.: 21

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Continuation of Box II.2

Claims Nos.: 1-21 in part

Present claims 1-21 relate to an extremely large number of possible pharmaceutical compositions, namely all those comprising active agent(s) "which have low solubility in water or are water-insoluble" (claim 1).

Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the compositions claimed, namely those wherein the active agent is a taxoid (particularly paclitaxel) within the meaning of claims 6 and 7. Compositions comprising other active agents, even if speculatively mentioned in a long list (cf. claim 4), cannot be considered to be sufficiently disclosed in the description, because it is not made credible or shown that the relevant technical problem is effectively solved in the same way for all of the active agents listed in claim 4.

In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the compositions as claimed in claim 1 in combination with claims 6 and 7.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

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